COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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May 9, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: *Medicare Program; Part B Drug Payment Model* [CMS-1670-P]

Dear Acting Administrator Slavitt:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), I am writing to submit our comments relating to the proposed rule on the *Medicare Program; Part B Drug Payment Model* [CMS-1670-P] (herein referred to as the "Part B Proposal"). For the reasons stated below, we strongly oppose the Part B Proposal and request it be withdrawn.

As COA has publically stated, and as I and other representatives from COA leadership voiced in a meeting with officials from the Centers for Medicare & Medicaid Services ("CMS") and the Center for Medicare & Medicaid Innovation ("CMMI"), we are vehemently opposed to the Part B Proposal. In short, we believe that not only is "Phase 1"[1] of the Part B Proposal (the "Part B Proposal Phase 1") an inappropriate, dangerous and perverse mandatory, national experiment on the cancer care of seniors who are covered by Medicare but also the Part B Proposal raises numerous insurmountable legal issues that have profound consequences.

We are appalled that CMS has marketed an ill-conceived attempt to control Part B drug prices by aggressively mounting a public relations campaign calling into question the motivations of oncologists. In the process, CMS has implied without basis that community oncologists are not providing their patients with the most appropriate, highest quality cancer care. CMS' questioning of the motivations of community oncologists is not productive in achieving constructive oncology payment reform.

Aside from the implications of the baseless statements by CMS, it is alarming that CMS is proposing to experiment on the cancer care provided to the nation's most vulnerable cancer patients—seniors and those individuals with disabilities covered under Medicare. Our first and foremost concern with this Part B Proposal is for our patients dealing with a terrible disease. Because of that, we intend to fight as hard for our patients to stop the Part B Proposal as we do every day for them in providing the highest quality, and most affordable, cancer care. For the sake of all of our patients—*and generations of cancer patients to come*—CMS must not proceed with

[1] Section 1115A of the Patient Protection and Affordable Care Act is divided into two parts or phases: (1) a phase 1 testing of models (referred to as phase 1); and (2) upon the completion of phase 1, an optional phase for the expansion of the duration and scope of a model being tested (referred to as phase 2). However, for the reasons discussed in this letter, the phase 1 of the Part B Proposal is not a phase 1 test as contemplated by Section 1115A.

the Part B Proposal. Please understand that it is not hyperbole when we say that we are pursuing every possible avenue to stop this dangerous experiment on cancer care, including legal action. Otherwise, the Part B Proposal will adversely impact the cancer care provided to Medicare patients and effectively treat them as second-class citizens by diminishing the highest quality medical treatment to which they are entitled under Medicare.

Before we summarize our opposition to the Part B Proposal and provide more detailed comments and documentation, I want to make one fact very clear: **No one can accuse community oncology, and COA specifically, of standing in the way of seeking solutions to the high costs of cancer therapies while ensuring that our patients receive the highest quality cancer care.** As the front-line providers for the majority of Americans with cancer, we understand better than anyone the realities and problems of the increasing cost of cancer care. For close to five (5) years, COA has been working with Medicare and private insurers in advancing payment reform in cancer care. For example, my practice and six (6) others participated in the CMMI Medicare *COME HOME* project based on the patient-centered Oncology Medical Home ("OMH") model that community oncologists created and continue to advance. Additionally, many community oncology practices are also very engaged in numerous payment reform projects with private payers including Aetna, Anthem, Cigna, Horizon, Humana, Priority, and UnitedHealthcare, to name a few. These projects are producing impressive results in both enhancing the quality of cancer care and reducing costs. During the past two (2) years, we have held major summits where close to two hundred (200) providers, payers, and industry representatives have come together to discuss oncology payment reform projects in the field and to share ideas in an open, cooperative information exchange forum.

Furthermore, COA has worked with the American College of Surgeons' Commission on Cancer to develop a thorough, tested accreditation program for the OMH. In the first pilot of this new program, my practice and eight (8) others across the country received OMH accreditation. COA also has a standing OMH Steering Committee, comprised of representatives from the patient, provider, and payer communities, which has identified, developed, and endorsed eighteen (18) measures of quality and value in cancer care. All of this ties to a model of payment reform that COA has developed, which is largely contained in the bipartisan congressional oncology payment reform bill, the *Cancer Care Payment Reform Act* (H.R. 1934), authored by Representatives Cathy McMorris Rodgers (R-WA) and Steve Israel (D-NY).

COA welcomes the opportunity to work with CMS and CMMI on constructive, holistic oncology payment reform initiatives. In fact, members of our Board, including me, have been very involved in the CMMI *Oncology Care Model* ("OCM") which has been over three (3) years in development. However, the Part B Proposal involved absolutely no stakeholder input in its construction and *literally appeared out of nowhere,* as oncology practices were waiting to be notified by CMMI of being accepted to participate in the OCM. Now, through the rule-making process, CMS is asking for comments on a "model" that was developed entirely by/within CMS. This entire process, as well as the premise of the Part B Proposal, violates both the spirit and the law of why CMMI was created, empowered, and funded by Congress.

Summary of the COA Position on the Part B Proposal

As we discuss in detail below, we object to the Part B Proposal because it is **bad medicine**, **flawed economics**, and **destructive policy**, as well as being **legally invalid**.

A. Medical, Economic and Policy Reasons the Part B Proposal Needs to be Withdrawn.

1. *The Part B Proposal is Bad Medicine.* If CMS had an understanding of modern-day cancer care, the agency would realize that there are very few instances where global substitution of a less expensive cancer drug is possible, appropriate, and safe. What CMS is doing in the Part B Proposal Phase 1 is blindly ratcheting down payment for standard-of-care cancer drugs in order to simply cut costs by trying to force oncologists to use less expensive, older therapies, which in some cases is not even possible. The Part B Proposal Phase 1 is to be conducted as an experiment that randomizes geography to test and control experimental cells, with three-quarters of the country in the test cell. The experiment is designed to change clinical decision-making to lower the cost of cancer drugs. However, unlike the accepted rules

and ethics of clinical research on human subjects, seniors covered by Medicare cannot opt out of the experiment and receive no "informed consent" that they are part of a clinical research experiment. It is also alarming that there are no patient safeguards, such as real-time monitoring and public reporting of adverse events, outcomes, and quality.

2. *The Part B Proposal is Flawed Economics.* CMS has already conducted an experiment on cancer care delivery by substantially cutting Medicare Part B drug reimbursement on two previous occasions. In 2005, CMS required pharmaceutical manufacturers to include wholesaler prompt pay discounts in the calculation of Medicare payment rates, which had the effect of artificially lowering Part B drug reimbursement. Then, in 2012, CMS decided to apply the Medicare sequester cut to underlying drug costs. The experiment in cutting Part B drug reimbursement has resulted in a dramatic shift of cancer care to the more expensive hospital setting. In 2004, 84% of chemotherapy was delivered in independent community cancer clinics, but by 2014 that had fallen to 54%, with the remainder delivered in the far more expensive hospital outpatient setting.[2] Financially, this has been documented as increasing costs to Medicare—in 2014, it cost Medicare $2 billion more for just chemotherapy than it would have been had the site-of-service not shifted to the hospital setting.[3] Furthermore, over the ten (10) plus year period that CMS has continued to cut Part B drug payments, cancer drug prices have *increased*, especially as the 340B drug discount program has grown exponentially—with 340B hospitals using more drugs or more expensive drugs.[4] Now CMS intends to cut Part B reimbursement yet again with the expressed purpose of lowering Medicare Part B costs and drug prices. **It is simply mind-boggling that CMS does not understand, based on empirical evidence, that the Part B Proposal will clearly increase Medicare costs and further fuel drug prices.**

3. *The Part B Proposal is Destructive Policy.* CMS is using Section 1115A of the Patient Protection and Affordable Care Act ("Section 1115A") to effectively overturn legislation that was passed by Congress and signed into law (the Medicare Modernization Act of 2003 ("MMA"), which fixed Medicare Part B drug reimbursement). If the Part B Proposal is implemented, the Executive branch could effectively overturn any Medicare law passed by Congress simply by creating a CMMI mandatory, national "model." That is exactly what CMS is doing with the Part B Proposal in now overturning the MMA that established by law Part B drug reimbursement at average sales price (ASP) plus 6%. CMS is using Section 1115A to effectively overturn the law to change Part B reimbursement to ASP plus 2.5% and a flat fee of $16.80 by implementing a national, mandatory "model." (We note for the record that although CMS proposes a reimbursement rate of ASP plus 2.5% and a fee of $16.80 it knows all too well that the sequester cut makes the proposed rate ASP plus 0.86% and $16.53 in reality.) The Part B Proposal sets a destructive and devastating policy precedent.

B. Legal Reasons the Part B Proposal is Invalid.

1. *The Part B Proposal Exceeds CMS' Statutory Authority.* In issuing the Part B Proposal, CMS relies on Section 1115A of the Patient Protection and Affordable Care Act ("ACA"). The Part B Proposal exceeds CMS' authority because, among other reasons: (A) the Part B Proposal is inconsistent with the express mandate of Section 1115A, (B) the Part B Proposal—by being mandatory in scope and affecting most of the nation—is not a test or model, and (C) the Part B Proposal appears not to be based upon a model developed by CMMI, but rather initiated outside of CMMI.

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[2] *Cost Drivers of Cancer Care: A Retrospective Analyses of Medicare and Commercially Insured Population Claim Data 2004-2014*, Milliman, April 2016.

[3] Id.

[4] *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.* The U.S. Government Accountability Office, July 2015.

2. *The Secretary*[5] *Has No Authority To Waive Medicare Provisions under the Part B Proposal.* As the Part B Proposal fails to meet the requirements for "testing," the Secretary has no authority to waive any requirements of the Medicare statute, especially the Part B payment provisions.

3. *The Part B Proposal Raises Constitutional Concerns.* Section 1115A would raise several constitutional concerns if the Secretary or CMS were allowed to modify or amend the Medicare statute, especially in view of the proposal's affect upon 75% of the country.

4. *The Part B Proposal Contravenes Other Applicable Laws.* The Part B Proposal violates Section 3601 of the ACA, as the implementation of the proposal would affect guaranteed Medicare benefits and other provisions.

As we expressed in a meeting with CMS and CMMI officials, COA is very open to working on value-based approaches to all facets of cancer care, including both services and drugs. However, for the reasons summarized above and explained below, the premise and design of the Part B Proposal is fundamentally flawed and must not be implemented. There is no way of changing the reimbursement scheme in the Part B Proposal Phase 1 to make it acceptable for oncologists to ensure that they can provide safe and effective cancer care. The Part B Proposal, by focusing on costs alone, is patently unacceptable, as it ignores the potential significant negative effects on quality and safety of patient care.

As with the OCM, CMS and CMMI must engage stakeholders, starting with patients and physicians, in an open, transparent, and constructive dialogue. The Part B Proposal Phase 1 must be withdrawn, and any discussions about a possible phase 2 must start with stakeholder input from the very beginning, not after CMS regulators have designed it internally.

Detailed Comments on the Part B Proposal

A. Medical, Economic and Policy Reasons the Part B Proposal Needs to be Withdrawn.

1. The Part B Proposal is Bad Medicine.

a. The Part B Proposal is in actuality a research experiment but without any of the required patient disclosure information and safeguards.

The purpose of the Part B Proposal Phase 1 is to change the clinical decisions of oncologists and other physicians, as we previously noted. Yet, patients cannot opt out of the experiment, and they do not receive any information about the research or their rights, let alone any protection from the experiment. There is no real-time monitoring of quality impacts, adverse treatment events, and treatment outcomes. We submit with this letter as Exhibit 1 an April 29, 2016 communication from Senator Charles Grassley to Secretary Sylvia Burwell and request that CMS answer the specific questions posed to Secretary Burwell about the research in the Part B Proposal.

b. The Part B Proposal inappropriately puts government regulators between physicians and patients in dictating clinical decision-making.

What this experiment is saying is that CMS believes it knows better than highly trained physicians and intends to influence or even dictate drug treatment choice rather than such choice residing with the patient's treating oncologist. As practicing physicians, we are in the best position to determine the care our patients should receive in close consultation with them—not federal government regulators. This experiment is a misguided government intrusion on the treatment of seniors with cancer and a very dangerous precedent in severing the sacred physician-patient bond.

[5] For purposes of the statute, "Secretary" is defined as the Secretary of Health and Human Services, *"except when the context otherwise requires."* 42 U.S.C. § 1301(6).

Make no mistake about it—CMS has designed the Part B Proposal not as a model of quality cancer care, like the OCM, but as a vehicle to circumvent existing law to lower Part B drug spending. However, in the process, it is inappropriately inserting itself between physicians and patients.

c. The Part B Proposal presents an experiment that is an operational nightmare and dangerous patient care, disadvantaging patients based on geography.

Given the enormity of implementing a national "model" for essentially all Medicare Part B drugs, CMS has clearly not considered the operational issues and implications for patient care. For example, it will be virtually impossible for CMS to ensure that every medical practice, not just community oncology practices, will be located entirely in either the test group or the control group. Given that practices have facilities in multiple states—for example, OHC, a community oncology practice based in Cincinnati, Ohio, has locations in two (2) states and serves patients from three (3) states—it will be virtually impossible to ensure practices are entirely in either test or control areas. This presents treatment dilemmas for the practice, not to mention a compromised experimental design. Furthermore, patients who receive treatment in two locations, especially seniors who live in both the south and north by season, will possibly be treated both in a test location and a control location. These are not just pure operational issues; these issues have serious implications for quality patient medical care.

It is not a solution to simply exempt the practices selected to participate in the OCM from the Part B Proposal. Not only does this compound the operational nightmare, but also the surprise release of the Part B Proposal demonstrates that CMS can change the rules whenever it pleases.

2. The Part B Proposal is Flawed Economics.

a. The underlying premise of the Part B Proposal Phase 1 is fundamentally flawed.

The Part B Proposal Phase 1 contemplates cutting payments for Medicare Part B drugs for three-quarters of the country from ASP plus 6% to ASP plus 2.5% and a flat fee. This proposal is grounded in the CMS implied assumption that community oncologists practice medicine based on financial incentives, not the best interests of their patients.[6] This is not only highly offensive and derogatory, but also simply not grounded in fact.

Rather than relying on untested assumptions not based on facts and analyses, CMS should examine a UnitedHealthcare study in which certain community oncology practices participated. This study was designed to eliminate any perceived "incentive" to prescribe cancer drugs by paying for those drugs at acquisition cost (in this case, ASP). By eliminating this perceived "incentive," UnitedHealthcare sought to reduce overall costs of chemotherapy. The results, however, proved just the opposite. According to the published study results, *"[e]liminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy."* In fact, drug spending increased by 179%.[7]

In another study that analyzed oncologists' prescribing under the current Medicare Part B drug reimbursement system, researchers found that, *"[c]hanges in reimbursement after the passage of MMA appear to had less of an impact on prescribing patterns in FFS* [fee-for-service] *settings than the introduction of new drugs and clinical evidence as well as other factors driving adoption of new practice patterns."*[8]

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[6] CMS states on page 16 of the Part B Proposal: *"we intend to achieve savings through behavioral responses to the revised pricing, as we hope that the revised pricing will remove any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. In other words, we believe that removing the financial incentive that may be associated with the higher add-on payments will lead to some reduction in expenditures during phase I of the proposed model. An exact estimate of the amount of savings that might be achieved through behavioral responses is not readily available."*

[7] *Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model.* Journal of Oncology Practice, July 2014.

[8] *Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?* Journal of Oncology Practice, September 2014.

Not only has CMS selectively chosen to ignore these findings, but the agency has also provided no substantive evidence to support its flawed assumption that oncologists prescribe more expensive cancer drugs due to financial "incentives."

We reiterate a point previously made in this letter: in 2004, when Congress changed to the current ASP-based system, 84% of chemotherapy was delivered in independent community cancer clinics. By 2014, that figure had fallen to 54%, with the remainder delivered in the hospital outpatient setting.[9] If community oncology practices are "profiting" from cancer drugs, as CMS contends, why is cancer care significantly migrating to hospitals?

b. CMS is completely ignoring the real driver of Medicare Part B cancer drug costs.

We are totally perplexed that in discussing its purpose for the Part B Proposal, CMS states in the proposed rule that the "*significant growth*" in Part B drug spending *"has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion respectively.*" So, why is CMS not focused on the hospital market where significant growth in spending has occurred, especially those that are "non-profit," yet extremely profitable, and 340B hospitals that now account for over 60% of all Part B hospital spending on cancer drugs?[10]

We note that 340B discounts on cancer drugs provide enormous financial incentive for hospitals to acquire community oncology practices and profit from the difference between drug cost and Part B reimbursement. With discounts on drugs that are typically 30-50%, the 340B program provides hospitals with upwards of 100% profit margins on cancer drugs. To put that in perspective, depending on the type of cancer treated when a 340B hospital acquires a five (5) physician community oncology practice, the hospital is able to bill significantly more for oncology drugs, providing significant additional pure profit annually on cancer drugs alone to the hospital. Add to this the higher service and facility fees billed under the Hospital Outpatient Prospective Payment System ("HOPPS"), and the profitability to the hospital increases even more, as costs to Medicare and seniors increase dramatically. A recent study by the Berkeley Research Group ("BRG") found that in 2014, 340B hospitals cost Medicare 51% more on a per beneficiary per day basis for chemotherapy compared to community oncology practices.[11]

Studies by Avalere Health, BRG, Milliman, The Moran Group, as well as the U.S. Government Accountability Office ("GAO") have specifically documented the higher cost of cancer care when delivered in outpatient hospital facilities. The cost to Medicare and beneficiaries is even higher in 340B hospitals, as reported by the GAO:

> *The financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns... Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has direct financial effects on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B drugs. Furthermore, this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries.*[12]

Another study by the GAO documented the significantly higher costs to beneficiaries and Medicare by the eleven (11) prospective payment systems ("PPS") exempt cancer hospitals ("PCH") compared with a comparable set of teaching hospitals. GAO found in part that:

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[9] See supra, n.2.

[10] *340B Growth and the Impact on the Oncology Marketplace: Update.* Berkeley Research Group, December 2015.

[11] Id.

[12] *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.* The U.S. Government Accountability Office, July 2015.

> *In 2012, Medicare payments—both inpatient and outpatient—were substantially higher at PCHs than at PPS teaching hospitals in the same geographic area for beneficiaries with the same diagnoses or services. GAO estimated that...Medicare outpatient payment adjustments to PCHs resulted in overall payments that were about 37 percent higher, on average, than payments Medicare would have made to PPS teaching hospitals for the same set of services... If, in 2012, PCH beneficiaries had received* inpatient and outpatient services at nearby PPS teaching hospitals—and the forgone outpatient adjustments were returned to the Supplementary Medical Insurance Trust Fund—Medicare may have realized annual savings of almost $0.5 billion. Until Medicare pays PCHs to at least, in part, encourage efficiency, Medicare remains at risk for overspending.[13]

We note that the PCHs were compared with teaching hospitals billing under the HOPPS and, therefore, cost beneficiaries and Medicare even more than cancer care provided in community oncology practices.

It is extremely disconcerting that CMS persists in its misguided focus on cutting drug and service reimbursements to community oncology practices while "turning a blind eye" to the unmistakable fact that the consolidation of our nation's cancer system into hospitals—especially those with 340B discounts—is what is really costing Medicare, seniors, and taxpayers more for cancer care.

In choosing to completely ignore the clear, documented consolidation of cancer care into the more expensive hospital setting, especially those with 340B discounts, CMS persists in accelerating cancer care cost increases with the misguided Part B Proposal.

c. The Part B Proposal will severely restrict use of new, standard-of-care cancer treatments.

Not only is the underlying premise of the Part B Proposal fundamentally flawed, but also its purpose of paying for "value" is equally flawed in modern-day cancer care. To illustrate this point, COA worked with practicing medical oncologists and practice administrators to model the impact of the Part B Proposal.

Table 1 included with this letter displays three (3) standard-of-care treatments (*i.e.*, cancer regimens) for specific cancers: breast, lung, and multiple myeloma. Table 1 shows (in red) the Part B Proposal reimbursement cuts for the initial cycle of treatment and also all cycles. This analysis shows the significant reimbursement cuts to the most highly valued cancer drugs and significant payment increases for the lowest valued ancillary drugs, which is the exact opposite of paying for value. Generic drugs such as diphenhydramine and dexamethasone, used to facilitate administration of the main cancer treatment drugs, such as Perjeta and Herceptin, will receive increased reimbursement, while the main treatment drugs receive decreased reimbursement.

Table 2 presents an analysis of over two hundred (200) drugs used in cancer treatment, including treatment drugs, supportive care agents, and treatment facilitating drugs. The analysis shows the drugs that would be cut and increased in payment in the Part B Proposal Phase 1. This list clearly shows that standard-of-care treatment drugs would be significantly cut in payment while older drugs and facilitating agents would be increased.

Table 3 presents a list of forty-seven (47) cancer drugs that would not only be cut in reimbursement but would be "underwater"—that is, reimbursed less than their acquisition costs. These represent some of the most frequently prescribed cancer treatment drugs precisely because they are evidence-based, standard-of-care therapies.

As CMS must be aware, there are very few situations in cancer treatment when alternative drugs exist that are differentiated in price/cost. So, the Part B Proposal, while ostensibly focused on controlling costs, is valuing less-important drugs—mostly facilitating agents—and not the most important, highest-valued cancer treatment drugs that are standard-of-care therapy. For example, Keytruda, the new immunotherapy that former President Jimmy Carter

[13] *Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency.* The U.S. Government Accountability Office, February 2015.

received as part of his treatment for metastatic melanoma, is significantly cut in reimbursement under the Part B Proposal and will be reimbursed at less than cost. Under the Part B Proposal, CMS is using financial disincentives to pressure physicians to not prescribe these newer therapies for seniors covered by Medicare, such as Keytruda, thus significantly reducing the "value" of the cancer care provided to Medicare beneficiaries.

One analysis from the Memorial Sloan Kettering Evidence Driven Drug Pricing Project presents three (3) different sets of cancer therapies purporting that each set is interchangeable.[14] Unfortunately, this analysis is inaccurate and the COA response to it is in Exhibit 2.

As a side note, despite our country being in the middle of an opioid crisis, it is ironic that controlled substances reimbursed under Part B, such as morphine, would receive substantial increases in reimbursement as displayed in Table 4. While Congress is working on legislation to tackle that crisis, it appears imprudent to increase reimbursement on controlled substances by almost 3,400% in one case. To us, this is further evidence that CMS, in a rush to create the Part B Proposal with no stakeholder input, has failed to understand the unintended consequences of its regulatory actions.

3. The Part B Proposal is Destructive Policy.

a. The Part B Proposal is a dangerous abuse of regulatory policy. CMS is inappropriately using section 1115A to effectively overturn existing law on Medicare Part B drug reimbursement.

The *Part B Proposal* is in not a "model" as conceived by Section 1115A, the provision which created, empowered, and financed CMMI. According to the ACA:

> *The purpose of the CMI* [CMMI] *is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).*[15]

Furthermore, Section 1115A of the ACA states:

> *In carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums . . .*[16]

CMMI has taken over three (3) years, and it has consulted with varied stakeholders, including oncologists, patients, and experts, to develop its oncology payment reform model, the OCM. In fact, members of the COA Board, including me, participated in a MITRE Corporation and Brookings Institution technical expert process in the development of the OCM. Our practice has been accepted to be a participant in the voluntary OCM. Although community oncologists have concerns about certain design aspects of it, the OCM was developed in a deliberative, thoughtful process by CMMI.

This stands in stark contrast to the Part B Proposal, which we do not believe was initiated or conceived by CMMI and has not involved any stakeholders or expert opinion, and clearly does not fit the intent of the ACA. According to Section 1115A of the ACA:

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[14] *Part B payment for drugs in Medicare: Phase 1 of CMS' proposed pilot and its impact on oncology care.* Memorial Sloan Kettering Evidence Driven Drug Pricing Project, April 2016.

[15] Section 1115A(a)(1).

[16] Section 1115A(a)(3).

> *The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.*[17] (emphasis added)

The Part B Proposal has nothing to do with outcomes or quality. It is simply a vehicle to circumvent Congress and its legislative action on Medicare Part B drug reimbursement—the MMA—that has defined Part B drug reimbursement as ASP plus 6%. This means that going forward CMS can use Section 1115A to effectively overturn any existing Medicare law by simply designing and implementing a mandatory, national "model" to circumvent the law. Then, after the "model" demonstration period is completed, the underlying "model" being tested becomes law: in this case, Medicare Part B drug reimbursement will change from ASP plus 6% to ASP plus 2.5% and a flat fee.

B. Legal Issues and Reasons the Part B Proposal is Invalid.

In issuing the Part B Proposal, CMS expressly relies on Section 1115A for authority.[18] According to Section 1115A, the Secretary cannot select for testing any model it chooses. The Secretary is permitted to select for testing only *"models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."*[19] In addition to these criteria, in phase 1 of a test the Secretary is required to undertake an evaluation of each model involving the *"quality of care furnished under the model, including measurement of patient-level outcomes . . . ,"* and changes in spending.[20] While the Secretary may waive specified statutory requirements in phase 1, such waiver is limited. The waiver applies only *"as may be necessary solely for purposes of carrying out"* (emphasis added) the testing in phase 1.[21]

If the Secretary elects to proceed to phase 2, Section 1115A expressly requires the Secretary to conduct rulemaking, and the Secretary may undertake phase 2 expansion only if the Secretary determines that such expansion is expected to reduce spending under Medicare without reducing the quality of care or improve the quality of patient care without increasing spending.[22] The Secretary cannot waive statutory requirements in phase 2 because the statute permits waivers *"solely for the purposes of testing."*[23]

Section 1115A was designed to encourage innovation in payment and service delivery models. However, this innovation is limited. For several reasons explained below, the Part B Proposal exceeds the statutory limits on phase 1 testing.

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[17] Section 1115A(b)(2)(A).

[18] In the Summary of the part B Proposal, CMS states *"[t]his proposed rule discusses the implementation of a new Medicare payment model under section 1115A of the Social Security Act (the Act)."* 81 FR 48, 13230.

[19] Section 1115A(b)(2)(A).

[20] Section 1115A(b)(4)(A)(i) and (ii).

[21] Section 1115A(d)(1) (*"The Secretary may waive [specified statutory requirements] as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)."*).

[22] Section 1115A(c).

[23] Section 1115A(d)(1).

1. **The Part B Proposal Exceeds CMS' Statutory Authority.**

a. The Part B Proposal is inconsistent with the express mandate of Section 1115A.

As discussed above, the Secretary cannot select for testing any model it chooses. The Secretary is permitted to select models for testing only where it determines *"deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."* This determination is to be made before selecting the models for testing, not during or after model testing. Having reviewed the Part B Proposal, we do not find evidence to suggest that the Secretary has made a determination of any deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.

Moreover, Section 1115A expressly requires that a phase 1 testing model address a *"defined population for which there are deficits in care."*[24] While the Part B Proposal establishes a test area—beneficiaries in approximately 75% of the country who take a Part B drug—this does not address the requirements of Section 1115A. Specifically, Section 1115A does not permit the selection or designation of any test area. Rather, the Secretary must have determined in advance that the group to be tested has deficits in care. Merely statistically selecting areas without regard to this determination fails to meet the statutory requirements. This Part B Proposal ignores the statutory requirements, as it would cover beneficiaries in approximately 75% of the country who take a Part B drug regardless of whether any of these beneficiaries has a "deficit in care." This is a random selection made without regard to the Secretary's statutory charge to select a "defined population" with "deficits in care."

More importantly, the Part B Proposal focuses on cost aspects of care, not the quality, sufficiency, or effect on care. The Part B Proposal is devoid of any significant reference to the effects on care, let alone the provision of findings with regard to existing deficits of care.

b. The Part B Proposal—by being mandatory in scope and affecting most of the nation—is not a test or model.

CMS proposes to subject 75% of the country to the Part B Proposal Phase 1. This proposal goes well beyond what could reasonably be considered a "test." A test is the essence of phase 1. Section 1115A contemplates a two-step process. A smaller test in phase 1, expanded through rule making if the following requirements are met:

> (1) *the Secretary determines that such expansion is expected to—*
>
> (A) *reduce spending under applicable title without reducing the quality of care; or*
>
> (B) *improve the quality of patient care without increasing spending;*
>
> (2) *the Chief Actuary of the Centers for Medicare and Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and*
>
> (3) *the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable titles for applicable individuals.*[25]

Despite the statutory mandate of Section 1115A, the Secretary has opted to bypass a controlled "test" geography, making this an "expansive" experiment affecting 75% of the country, without addressing the requirements set forth

[24] Section 1115A(b)(2)(A).

[25] Section 1115A(c)(1)-(3).

above. It is clear that by reading Section 1115A as a whole these requirements are expressly imposed upon the Secretary before it can make a test expansive, and these requirements cannot be ignored.[26]

While CMS cites to a recent report of MedPAC[27] with regard to a suggested add-on model, it does not focus on an earlier 2012 MedPAC report, which discussed a concern about the scope of a test related to Medicare-Medicaid dual eligible models. Even though the planned scope of the dual eligible models was much smaller than the Part B Proposal—about 1/3 of dual eligibles—MedPAC expressed concern with the sample size as follows:

> *Most states pursuing the capitated model are proposing to enroll most or all dual-eligible beneficiaries in a state or entire subgroups of beneficiaries (such as disabled individuals under the age of 65) in a state into a* [demonstration] *health plan. However, the varied and complex needs of many of these individuals leads us to question whether care management models should be tested on large numbers of dual-eligible beneficiaries or entire subgroups within a state. In addition, the large scope also makes the demonstrations appear to be large-scale program changes rather than true demonstrations.*[28] (emphasis added)

Beyond the MedPAC report expressing alarm with regard to large test populations, courts have also stressed the need for tests to be of a controlled size and duration.[29]

The Part B Proposal goes well beyond a geography of limited duration and is exactly the type of test arrangement with respect to which MedPAC and the courts have expressed concern. Accordingly, the mandatory nature of a test constituting of 75% of the county is well beyond what the courts, MedPAC, and others have considered acceptable for testing and thus cannot constitute a test.

c. *The Part B Proposal appears not to be based upon a model developed by CMMI, but rather initiated outside of CMMI.*

Section 1115A provides for the creation of CMMI within CMS. CMS itself has explicitly recognized the mandate for CMMI to develop models:[30] *"[p]ayment and service delivery models are developed by CMMI in accordance with the requirements of section 1115A of the Act. During the development of new models, CMMI builds on the ideas received from internal and external stakeholders and consults with clinical and analytical experts."*[31]

Despite the requirement that CMMI develop the models, CMS Deputy Administrator and Medicare Director Sean Cavanaugh was recently quoted in an article appearing in InsideHealthPolicy on April 28, 2016. This article states that on April 11, 2016, in response to a question about whether President Obama personally directed CMS to weigh in on Part B drug prices with a pilot program, Mr. Cavanaugh stated *"[y]ou're correct, . . . [t]he president has been very*

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[26] "It is, however, a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute." Williams v. Taylor, 529 U.S. 362, 404 (2000) (internal quotations and citations omitted).

[27] See 81 FR 48, 13231 (citing MedPAC Report to the Congress: Medicare and the Health Care Delivery System (June 2015)).

[28] MedPAC, Report to the Congress: Medicare and the Health Care Delivery System (June 2012) at 64 (emphasis added).

[29] See Bay Ridge Diagnostic Laboratory, Inc. v. Dumpson, 400 F. Supp. 1104 (E.D.N.Y. 1975) (implementation of the program in limited locality under Section 1115); Am. Acad. Of Ophthalmology, Inc. v. Sullivan, 998 F.2d 377, 384 (6th Cir. 1993) (finding that "[t]he Demonstration does not alter or modify the whole Medicare program, it does not affect Medicare's coverage of all medical services, medical items, and health care provides. Instead, the Demonstration touches only cataract surgeries and, in fact, only specified varieties of cataract surgeries. Further, patient as well as health care provider participation is strictly voluntary in the Demonstration.") (emphasis added).

[30] Section 1115A further provides that *"[i]n carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties."* Section 1115A(a)(3).

[31] 80 FR 132, 39869.

supportive generally of the value agenda at CMS, and all of HHS for that matter, and was very much one to say 'don't leave out prescription drugs.'"[32]

CMS has publicly stated that CMMI is responsible for developing models, yet the statements of the Administration suggest strongly that CMMI did not develop this model. Accordingly, the Part B Proposal would not constitute a "model" under Section 1115A.

2. The Secretary Has No Authority to Waive Medicare Provisions under the Part B Proposal.

In order for the Secretary to have the authority to "waive" requirements of Medicare, the Secretary must be doing so "*solely for the purpose of carrying out this Section with respect to testing models described in subsection (b).*" (emphasis added).[33] The Secretary has opted to bypass a limited test phase, instead implementing what amounts to a program change affecting, on a mandatory basis, 75% of the country.

Section 1115A (b) (4) is clear that any waiver authority of the Secretary applies solely with respect to testing. As we have earlier discussed, the Part B Proposal is not a phase 1 "test," and, accordingly, the Secretary cannot use any waiver authority for this model. Thus, any attempt to change the reimbursement method for Part B drugs does not apply.

3. The Part B Proposal Raises Constitutional Concerns.

For the reasons described above, the Secretary cannot use the waiver authority in Section 1115A in the manner proposed. Assuming for the sake of argument that the Section 1115A waiver provision did apply to the Part B Proposal and permitted the Secretary to waive the applicable Medicare provisions—which we dispute—the attempted exercise of any such authority would raise serious constitutional concerns.

a. The waiver provision violates Article I of the Constitution.

The Secretary's proposal to waive the statutory payment mechanism for Part B drugs and substitute a new payment methodology through the Part B Proposal is effectively a repeal of a statutory provision of the Medicare statute and enactment of what amounts to new statutory language. This raises significant constitutional concerns. The Supreme Court has recognized that *"repeal of statutes, no less than enactment, must conform to Art. I."*[34] Under the Constitution, legislation must be passed by both the House and Senate and signed by the President absent the override of a veto.[35] These constitutional requirements also apply to repealing existing legislation.[36] Following this constitutional principle, the Supreme Court struck down the Line Item Veto Act, which permitted the President to cancel certain provisions of duly enacted statutes.[37]

If Section 1115A were interpreted to permit the waivers in the Part B Proposal, Section 1115A would have the same constitutional concerns as the Line Item Veto Act. Also, it would present the added issue of CMS attempting to enact new statutory language to replace the provisions of the Medicare statute that the Secretary or CMS proposed to "waive" (*i.e.*, repeal).

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[32] InsideHealthPolicy, April 28, 2016.

[33] Section 1115A(d)(1).

[34] INS. v. Chadha, 462 U.S. 919, 954 (1983).

[35] U.S. Const., art. I, § 7.

[36] Chadha, 462 U.S. at 954.

[37] Clinton v. City of New York, 524 U.S. 417 (1998).

b. The Part B Proposal raises additional constitutional concerns.

CMS bases its authority for the Part B Proposal on Section 1115A, which can be viewed as an unconstitutional delegation of legislative power. Article I, Section 1 of the Constitution prohibits Congress from delegating its legislative powers to other bodies, including executive agencies like CMS.[38] Given this constitutional constraint, if Congress seeks to delegate its legislative power to an executive agency like CMS, the legislation must contain an "intelligible principle" to guide the agency's decision-making.[39] The requisite specificity of the "intelligible principle" depends on the amount of power that Congress is delegating.[40] In other words, the more power Congress is delegating, the more specific its guidance must be.[41] If the interpretation CMS proposes to give to Section 1115A is correct, then, in drafting Section 1115A, Congress failed to provide a sufficiently specific intelligible principle to CMS and CMMI to guide its decision making (including with regard to the waiver authority), and, consequently, Section 1115A as interpreted by CMS and the Part B Proposal would be unconstitutional.

Further, the Part B Proposal denies those beneficiaries and others who are forced to participate in the Part B Proposal the potential right to equal protection of the laws in violation of the Due Process Clause of the Fifth Amendment to the Constitution. The beneficiaries and others who are forced to participate in the model are not treated equally with those who are not required to participate. As explained above, among other things, the beneficiaries forced to participate will run the risk of receiving less favorable care than those beneficiaries who are not compelled to participate. Even assuming that the Part B Proposal is authorized by Congress, it is one situation to have a congressionally authorized, limited "test" of a new payment methodology. It is quite another situation to propose a scheme that treats 75% of the country disparately from the other 25%. The latter is, at a minimum, an abuse of discretion; and, more importantly, a direct violation of the right to equal protection of the laws.

Moreover, courts have long recognized the need to narrowly construe statutes to avoid constitutional challenge. CMS' interpretation of the statute to permit a large-scale application of the Part B Proposal to 75% of the country and implementation on a mandatory basis is inconsistent with the concept of a "test," and the language of the statute would need to be construed narrowly to avoid a violation of the Constitution.

4. The Part B Proposal Contravenes Other Applicable Laws.

a. The Part B Proposal contravenes Section 3601 of the ACA.

Even if CMS could be found to have the authority to implement the Part B Proposal and Section 1115A could be found to pass Constitutional muster, neither of which we believe, the Part B Proposal would violate Section 3601 of the ACA ("Section 3601"), as the implementation of the Part B Proposal would affect "guaranteed" Medicare benefits. Section 3601 prohibits another provision of the ACA from reducing "guaranteed benefits" under Medicare. Specifically, Section 3601 states:

> *Protecting Guaranteed Medicare Benefits. Nothing in the provisions of, or amendments made by, this Act shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act.*[42]

The Medicare statute expressly covers the provision of drugs under Part B of the Medicare law. While the term "guaranteed benefits" is not defined by Section 3601, beneficiaries are entitled to coverage for Part B drugs by

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[38] Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001) (internal quotation omitted).

[39] Id.

[40] Id. at 475.

[41] Id.

[42] Pub. L. No. 111-148 (2010).

Medicare and, as such, these benefits are "guaranteed" to beneficiaries.[43] Moreover, this provision embodies the assurance that the ACA would not reduce "guaranteed benefits" as advanced by the legislative members and the President when the passage of the ACA was being considered. Effectively, through the Part B Proposal, CMS is creating a mechanism for it to influence clinical decision-making and direct patients away from a guaranteed benefit. The consequences of CMS' proposal would be a violation of Section 3601.

b. The Part B Proposal likely contravenes other laws.

Beyond the contravention of Section 3601, the Part B Proposal contravenes other laws. Among other things, the Part B Proposal likely impairs a Medicare beneficiary's right to select health care services as guaranteed under the Medicare Act. Specifically, 42 U.S.C. § 1395a provides:

> *Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services.*[44]

As we discussed earlier, the Part B Proposal attempts to steer physicians to select lower cost drugs for patients. Beneficiaries desiring these drugs from a particular physician may not be able to obtain them because of CMS' financial penalties imposed by the Part B Proposal upon the prescribing physician and, thus, the Part B Proposal impairs the beneficiary's selection right.

Closing Comments

I want to reiterate that community oncology providers stand ready to work with CMS and CMMI on true oncology payment reform, as we have been leading the way for close to five (5) years. Nothing in this letter should convey that we object to appropriate value-based payments in cancer care, for either drugs or services. In fact, COA has been working on measuring quality and value in cancer care and developing new payment models based on the delivery of value. We believe that there are potential applications of concepts such as value-based insurance design to the treatment of cancer care, not just diagnosis.

We are very concerned about the increased cost of cancer care, especially escalating prices of drugs. However, we call CMS' attention to the study by Milliman on the cost drivers of cancer care previously cited in this letter. Although drugs are the most rapidly increasing cost component of cancer care, they only account for upwards of 20% of total spending on cancer care.[45] Thus, a Herculean effort that would reduce drug spending by 25% would only reduce overall costs of cancer care by 5%. Therefore, it is critical that CMS take a holistic view and consider all of the cost drivers of cancer care, including the increased attribution to the site of cancer care delivery.

Please understand that we are actively pursuing every legal, legislative, and related option to stop the Part B Proposal. For the sake of our patients, we simply cannot let CMS proceed with the dangerous Part B Proposal Phase 1, which is not a true "model" in the CMMI legislative charter, but rather a perverse and unethical experiment on the care provided to the nation's most vulnerable cancer patients—seniors and those individuals with disabilities covered under Medicare.

If you would like to set up time to discuss any of these comments further, arrange an in-person meeting, or have any questions answered, I can be contacted directly at big83@ngoc.com or through the COA offices at (202) 756-2258. You can also contact COA Executive Director Ted Okon at tokon@COAcancer.org or at (757) 822-6134.

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[43] See 42 U.S.C. §§ 1832 and 1842.

[44] 42 U.S.C. § 1395a(a).

Sincerely,

Bruce J. Gould MD

Bruce Gould, MD
President

CC:
The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
U.S. House of Representatives

REPLY TO:
☐ 135 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-1501
(202) 224-3744
www.grassley.senate.gov

☐ 721 FEDERAL BUILDING
210 WALNUT STREET
DES MOINES, IA 50309-2106
(515) 288-1145

☐ 111 7TH AVENUE, SE, BOX 13
SUITE 6800
CEDAR RAPIDS, IA 52401-2101
(319) 363-6832

EXHIBIT 1

United States Senate

CHARLES E. GRASSLEY

WASHINGTON, DC 20510-1501

April 29, 2016

REPLY TO:
☐ 120 FEDERAL BUILDING
320 6TH STREET
SIOUX CITY, IA 51101-1244
(712) 233-1860

☐ 210 WATERLOO BUILDING
531 COMMERCIAL STREET
WATERLOO, IA 50701-5497
(319) 232-6657

☐ 201 WEST 2ND STREET
SUITE 720
DAVENPORT, IA 52801-1817
(563) 322-4331

☐ 307 FEDERAL BUILDING
8 SOUTH 6TH STREET
COUNCIL BLUFFS, IA 51501-4204
(712) 322-7103

VIA ELECTRONIC TRANSMISSION

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: 42 CRF Part 511 Medicare Program; Part B Drug Payment Model; Proposed Rule

Dear Secretary Burwell:

On March 11, 2016 the Centers for Medicare Medicaid Services (CMS) issued a proposed rule for comment. The proposed rule puts forward for consideration a new Medicare payment model under section 1115A of the Social Security Act (SSA). The proposal is a two-phase model that would test whether an alternative drug payment system will lead to a reduction in Medicare Part B expenditures. The first phase would involve reducing the 6 percent add-on to the Average Sales Price (ASP) that is currently used to a 2.5 percent add-on plus a flat fee. The second phase would test the use of value-based purchasing tools[1].

I am concerned that throughout this proposed rule two terms are repeatedly used - "study" and "test." These terms seem to indicate there is a component of research going on in this proposal. I am writing you today to see if that is true and if that is true, are adequate protections in place for the Medicare beneficiaries who will be research participants.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral research wrote the Belmont Report[2]. This landmark document was the foundation for U.S. federal policy for the protection of human subjects in research. This policy was published as the "Common Rule" in 1991 and then codified through regulation (45 CFR part 46, subpart A) to apply to all of the departments and agencies listed below:

Agency for International Development

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

Consumer Product Safety Commission
Department of Agriculture
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of Justice
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
National Aeronautics and Space Administration
National Institute of Standards and Technology
National Science Foundation[3]

In addition, the following departments and agencies must also comply with 45 CFR part 46:

Central Intelligence Agency
Department of Homeland Security
Social Security Administration

Among other protections, the Common Rule requires any researcher to obtain "legally effective informed consent"[4]. Furthermore, the law says a person participating in research should do so of his or her own free will. Undue influence or coercion to participate in a study is prohibited.

It is my understanding that there are certain exceptions that allow government agencies to perform research without the informed consent of an individual. One exception is "research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures;
(iv) possible changes in methods or levels of payment for benefits or services under those programs[5].

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

However, it is my understanding that the proposed study for Part B of Medicare will be testing the hypothesis that a change in payment methodology will change a doctor's prescribing habits resulting in a Medicare beneficiary receiving a different medication. To me, that seems to be going beyond the intention of the exception in the Common Rule. By randomizing people to different payment methodologies, it seems possible that patients might receive a drug that is less effective for them. And, that seems to be a clinical trial. Therefore, please answer the following:

1. Is the Medicare Part B proposal research? If not, why not?
2. If this is research, how do you intend to obtain legally effective informed consent?
3. If this is research, how does HHS intend to collect and report adverse events?
4. If this is research, does HHS need to report findings at ClinicalTrials.gov?
5. If the results of this study are negative, that is it fails to show savings in Part B, will the results be made public?
6. Does HHS have any responsibility to inform physicians that they are participating in research? If not, why not?
7. Have other study designs to evaluate payment change been considered?

Please contact my staff, Karen Summar, with questions and with your answers.
Karen_Summar@Grassley.Senate.Gov

Sincerely,

Chuck Grassley

Charles E. Grassley
U.S. Senator

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

Cc: Andrew Slavitt, Acting Adminstrator, Centers for Medicare and Medicaid Services
Patrick Conway, M.D., MSc, Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer
Jerry Menikoff, M.D., Director of the Office for Human Research Protections (OHRP), HHS

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

TABLE 1_Impact of Medicare Part B Payment Model: Regimen Analysis**

Her 2 Positive Adjuvant or Neo adjuvant Breast *	Initial Cycle ASP +.86% + $16.53 per drug Less ASP + 4.304%	All Cycles ASP +.86% + $16.53 per drug Less ASP + 4.304%
Perjeta	($268.40)	($898.05)
Herceptin	($187.42)	($2,486.94)
Neulasta	($110.13)	($660.78)
Taxotere	$6.06	$36.36
Carboplatin	$15.36	$92.16
Aloxi	$9.29	$55.74
Benadryl	$16.51	$280.67
Dexamethasone	$16.42	$98.52
1 cycle every 3 weeks for 6 cycles followed by 11 cycles of just Herceptin every 3 weeks	-$502.31	-$3,482.32

Recurrent Metastatic Lung	Initial Cycle ASP +.86% + $16.53 per drug Less ASP + 4.304%	All Cycles ASP +.86% + $16.53 per drug Less ASP + 4.304%
Avastin	(214.02)	(1,284.12)
Alimta	(163.82)	(2,293.48)
Carboplatin	15.36	92.16
Aloxi	9.29	130.06
Dexamethasone	16.42	229.88
1 cycle every 3 weeks for 6 cycles followed by 6 to 8 month of Alimta management every 3 weeks (Could be indefinite or until patient progresses)	(336.77)	(3,125.50)

2nd Line Multiple Myeloma	Initial Cycle ASP +.86% + $16.53 per drug Less ASP + 4.304%	All Cycles ASP +.86% + $16.53 per drug Less ASP + 4.304%
Kyprolis	($526.50)	($6,318.00)
Dexamethasone	$98.52	$1,182.24
Zofran	$99.00	$1,188.00
Day 1,2, 8, 9, 15, 16 =1 cycle and starts over next month - open ended usually at least going for 1 year	($328.98)	($3,947.76)

*Initial Cycle includes loading dose for Perjeta and Herceptin

** All payment rates are net of sequestration

Changes in Reimbursement under CMS ASP Experiment - Per Administration - Corrected 5/10/16				
HCPCS Code	Short Description	Reimbursement per Dose ASP+4.3%	Reimbursement per Dose ASP+0.86%+$16.53	Difference Old to New
Q2043	Sipuleucel-T auto CD54+	37,733.75	36,504.35	(1229.39)
J9228	Ipilimumab injection	35,470.35	34,315.69	(1154.66)
J1300	Eculizumab injection	21,374.21	20,684.98	(689.22)
J9266	Pegaspargase injection	18,260.84	17,674.41	(586.42)
J9042	Brentuximab vedotin inj	16,369.56	15,845.59	(523.97)
J1786	Imuglucerase injection	15,333.14	14,843.39	(489.75)
J3385	Velaglucerase alfa	13,506.37	13,076.94	(429.43)
J0180	Agalsidase beta injection	11,986.99	11,607.73	(379.27)
J9307	Pralatrexate injection	9,506.06	9,208.71	(297.35)
J9043	Cabazitaxel injection	8,516.10	8,251.44	(264.66)
J9271	Inj pembrolizumab	8,276.80	8,020.04	(256.76)
J9302	Ofatumumab injection	8,242.43	7,986.80	(255.62)
NOC	Cyramza,ramucirumab, 100 mg	8,192.04	7,938.08	(253.96)
J9315	Romidepsin injection	7,893.37	7,649.27	(244.10)
J9354	Inj, Ado-trastuzumab Emt 1mg	7,563.74	7,330.53	(233.21)
NOC	Yondelis, 1mg	7,462.95	7,233.06	(229.89)
NOC	Keytruda injection, 1 mg	6,931.26	6,718.93	(212.33)
J2562	Plerixafor injection	6,640.64	6,437.90	(202.74)
J9306	Injection, Pertuzumab, 1 mg	6,471.96	6,274.80	(197.17)
J9299	Injection, nivolumab	5,952.00	5,772.00	(180.00)
J9310	Rituximab injection	5,833.30	5,657.22	(176.08)
J9308	Injection, ramucirumab	5,833.23	5,657.15	(176.08)
NOC	Opdivo, nivolumab, 1 mg	5,773.52	5,599.42	(174.10)
J9305	Pemetrexed injection	5,492.37	5,327.55	(164.82)
J2783	Rasburicase	5,047.25	4,897.13	(150.12)
J2323	Natalizumab injection	5,029.40	4,879.86	(149.53)
J1930	Lanreotide injection	5,005.23	4,856.50	(148.74)
J9303	Panitumumab injection	4,729.01	4,589.40	(139.62)
J2353	Octreotide injection, depot	4,561.50	4,427.42	(134.08)
J9033	Bendamustine injection	4,051.42	3,934.18	(117.24)
J9207	Ixabepilone injection	4,018.29	3,902.14	(116.15)
J1745	Infliximab injection	3,837.88	3,727.69	(110.19)
J2505	Injection, pegfilgrastim 6mg	3,836.03	3,725.90	(110.13)
J2792	Rho(D) immune globulin h, sd	3,710.22	3,604.25	(105.98)
NOC	Irinotecan, Liposome (Onivyde) 1mg	3,581.29	3,479.57	(101.72)
J0490	Belimumab injection	3,364.16	3,269.61	(94.55)
J1561	Gamunex-C/Gammaked	3,329.27	3,235.87	(93.40)
J9301	Obinutuzumab inj	3,296.62	3,204.30	(92.32)
J9355	Trastuzumab injection	3,211.91	3,122.39	(89.52)
J1568	Octagam injection	3,077.34	2,992.26	(85.08)
J0129	Abatacept injection	3,029.49	2,945.99	(83.50)
J1459	Inj IVIG privigen 500 mg	2,924.85	2,844.81	(80.04)
J1556	Inj, Imm Glob Bivigam, 500mg	2,914.33	2,834.63	(79.70)
J9055	Cetuximab injection	2,888.84	2,809.99	(78.86)
J9098	Cytarabine liposome inj	2,835.21	2,758.13	(77.08)
J1572	Flebogamma injection	2,824.00	2,747.28	(76.71)
J1569	Gammagard liquid injection	2,811.51	2,735.21	(76.30)
Q2050	Doxorubicin inj 10mg	2,788.18	2,712.65	(75.53)
J1557	Gammaplex injection	2,633.59	2,563.17	(70.43)
J9400	Inj, ziv-aflibercept, 1mg	2,587.26	2,518.36	(68.90)
J1566	Immune globulin, powder	2,556.76	2,488.87	(67.89)
J9179	Eribulin mesylate injection	2,505.37	2,439.17	(66.19)
J0630	Calcitonin salmon injection	2,331.23	2,270.78	(60.44)
J2796	Romiplostim injection	2,221.74	2,164.92	(56.83)

Changes in Reimbursement under CMS ASP Experiment - Per Administration - Corrected 5/10/16				
HCPCS Code	Short Description	Reimbursement per Dose ASP+4.3%	Reimbursement per Dose ASP+0.86%+$16.53	Difference Old to New
NOC	Darzalex, 100 mg	2,216.13	2,159.49	(56.64)
J3262	Tocilizumab injection	2,167.60	2,112.56	(55.04)
J9264	Paclitaxel protein bound	2,053.45	2,002.17	(51.27)
J8705	Topotecan oral	1,988.53	1,939.40	(49.13)
J9328	Temozolomide injection	1,957.34	1,909.25	(48.10)
J2357	Omalizumab injection	1,935.88	1,888.49	(47.39)
J1950	Leuprolide acetate /3.75 MG	1,930.84	1,883.62	(47.22)
J0485	Belatacept injection	1,897.51	1,851.39	(46.12)
J9047	Injection, Carfilzomib, 1 mg	1,853.78	1,809.10	(44.68)
J9395	Injection, Fulvestrant	1,776.38	1,734.25	(42.12)
J9268	Pentostatin injection	1,604.85	1,568.39	(36.46)
J9330	Temsirolimus injection	1,555.39	1,520.56	(34.83)
J9041	Bortezomib injection	1,515.60	1,482.09	(33.51)
J3240	Thyrotropin injection	1,434.66	1,403.82	(30.84)
J0897	Denosumab injection	1,310.23	1,283.50	(26.73)
J9035	Bevacizumab injection	1,298.74	1,272.39	(26.35)
J0894	Decitabine injection	1,099.12	1,079.35	(19.76)
J9017	Arsenic trioxide injection	932.66	918.39	(14.26)
J0641	Levoleucovorin injection	916.27	902.55	(13.72)
P9047	Albumin (human), 25%, 50ml	887.11	874.35	(12.76)
J0881	Darbepoetin alfa, non-esrd	871.18	858.95	(12.23)
J9217	Leuprolide acetate suspnsion	821.09	810.51	(10.58)
J1439	Inj ferric carboxymaltos 1mg	812.49	802.20	(10.30)
J3315	Triptorelin pamoate	809.19	799.00	(10.19)
J9214	Interferon alfa-2b inj	736.96	729.15	(7.80)
J9202	Goserelin acetate implant	695.93	689.48	(6.45)
J9280	Mitomycin injection	665.71	660.26	(5.45)
J1190	Dexrazoxane HCl injection	595.11	592.00	(3.12)
J2794	Risperidone, long acting	530.13	529.16	(0.97)
J9025	Azacitidine injection	510.61	510.28	(0.33)
J9070	Cyclophosphamide 100 MG inj	496.66	496.80	0.13
J0878	Daptomycin injection	467.77	468.86	1.09
Q5101	Inj filgrastim g-csf biosim	438.64	440.69	2.05
J0885	Epoetin alfa, non-esrd	424.67	427.18	2.51
Q0138	Ferumoxytol, non-esrd	420.11	422.77	2.66
J1442	Inj filgrastim excl biosimil	418.04	420.76	2.73
J9155	Degarelix injection	408.18	411.23	3.05
J2597	Inj desmopressin acetate	331.86	337.43	5.57
J2820	Sargramostim injection	324.81	330.62	5.81
J1740	Ibandronate sodium injection	307.40	313.78	6.38
J9150	Daunorubicin injection	277.50	284.87	7.37
J1453	Fosaprepitant injection	266.98	274.69	7.72
J9171	Docetaxel injection	251.43	259.66	8.23
J2997	Alteplase recombinant	249.78	258.06	8.28
J9065	Inj cladribine per 1 MG	232.16	241.03	8.87
J8530	Cyclophosphamide oral 25 MG	228.27	237.27	8.99
J2469	Palonosetron hcl	219.13	228.42	9.30
J0887	Epoetin beta esrd use	194.71	204.82	10.10
J2354	Octreotide inj, non-depot	152.40	163.90	11.50
J9293	Mitoxantrone hydrochl / 5 MG	145.44	157.17	11.73
J9031	Bcg live intravesical vac	121.03	133.56	12.54
J1750	Inj iron dextran	118.19	130.82	12.63
J9263	Oxaliplatin	116.20	128.90	12.69
J1447	Inj tbo filgrastim 1 microg	101.63	114.81	13.18

Changes in Reimbursement under CMS ASP Experiment - Per Administration - Corrected 5/10/16				
HCPCS Code	Short Description	Reimbursement per Dose ASP+4.3%	Reimbursement per Dose ASP+0.86%+$16.53	Difference Old to New
J9208	Ifosfamide injection	99.64	112.88	13.24
J9351	Topotecan injection	96.64	109.98	13.34
J2805	Sincalide injection	90.35	103.90	13.55
J3489	Zoledronic Acid 1mg	88.60	102.21	13.61
J9178	Inj, epirubicin hcl, 2 mg	83.88	97.65	13.76
J9185	Fludarabine phosphate inj	83.45	97.22	13.78
J1335	Ertapenem injection	82.24	96.06	13.82
J9201	Gemcitabine hcl injection	62.87	77.33	14.46
J8521	Capecitabine, oral, 500 mg	56.91	71.56	14.65
J2310	Inj naloxone hydrochloride	54.67	69.40	14.73
J1170	Hydromorphone injection	54.03	68.78	14.75
J9206	Irinotecan injection	49.47	64.37	14.90
J1756	Iron sucrose injection	47.89	62.84	14.95
J1050	Medroxyprogesterone acetate	45.01	60.06	15.04
J9390	Vinorelbine tartrate inj	44.17	59.25	15.07
J0834	Cosyntropin cortrosyn inj	42.91	58.02	15.11
J0640	Leucovorin calcium injection	38.85	54.10	15.25
J1652	Fondaparinux sodium	37.34	52.64	15.30
J8520	Capecitabine, oral, 150 mg	36.53	51.86	15.32
J9209	Mesna injection	33.30	48.73	15.43
J9130	Dacarbazine 100 mg inj	30.63	46.15	15.52
J9360	Vinblastine sulfate inj	30.22	45.75	15.53
J2430	Pamidronate disodium /30 MG	28.67	44.25	15.58
J9040	Bleomycin sulfate injection	25.84	41.52	15.68
J0895	Deferoxamine mesylate inj	25.46	41.15	15.69
J9045	Carboplatin injection	24.17	39.90	15.73
J2916	Na ferric gluconate complex	23.74	39.49	15.75
J9267	Paclitaxel injection	23.58	39.33	15.75
J9000	Doxorubicin hcl injection	22.74	38.52	15.78
90714	Td vaccine no prsrv >/= 7 yo, im	21.72	37.53	15.81
J9218	Leuprolide acetate injeciton	20.65	36.50	15.85
Q2037	Fluvirin vacc, 3 yrs & >, im	15.62	31.63	16.02
J3430	Vitamin k phytonadione inj	14.07	30.13	16.07
J0735	Clonidine hydrochloride	12.87	28.97	16.11
Q2035	Afluria vacc, 3 yrs & >, im	12.82	28.92	16.11
J9060	Cisplatin 10 MG injection	12.37	28.49	16.12
J0692	Cefepime HCl for injection	12.18	28.31	16.13
Q2038	Fluzone vacc, 3 yrs & >, im	12.17	28.30	16.13
Q9967	LOCM 300-399mg/ml iodine,1ml	12.07	28.20	16.13
J0780	Prochlorperazine injection	11.92	28.06	16.14
J9370	Vincristine sulfate 1 MG inj	11.78	27.93	16.14
J1650	Inj enoxaparin sodium	11.38	27.53	16.16
J9100	Cytarabine hcl 100 MG inj	11.28	27.44	16.16
J9181	Etoposide injection	10.52	26.71	16.18
J7613	Albuterol non-comp unit	10.43	26.62	16.19
J9190	Fluorouracil injection	9.99	26.19	16.20
J0360	Hydralazine hcl injection	9.19	25.42	16.23
J3370	Vancomycin hcl injection	8.54	24.79	16.25
J1450	Fluconazole	8.41	24.67	16.25
J1720	Hydrocortisone sodium succ i	8.08	24.34	16.26
J1940	Furosemide injection	7.93	24.20	16.27
J1642	Inj heparin sodium per 10 u	6.61	22.92	16.31
J1030	Methylprednisolone 40 MG inj	6.18	22.51	16.33
J1071	Inj testosterone cypionate	5.55	21.90	16.35

Changes in Reimbursement under CMS ASP Experiment - Per Administration - Corrected 5/10/16				
HCPCS Code	Short Description	Reimbursement per Dose ASP+4.3%	Reimbursement per Dose ASP+0.86%+$16.53	Difference Old to New
J1956	Levofloxacin injection	5.36	21.71	16.35
J2930	Methylprednisolone injection	4.97	21.34	16.37
J2175	Meperidine hydrochl /100 MG	4.85	21.22	16.37
J2920	Methylprednisolone injection	4.07	20.47	16.40
J3260	Tobramycin sulfate injection	3.99	20.39	16.40
J3420	Vitamin b12 injection	3.82	20.23	16.41
J0610	Calcium gluconate injection	3.66	20.07	16.41
J7070	D5w infusion	3.37	19.79	16.42
J1626	Granisetron hcl injection	3.32	19.74	16.42
J3411	Thiamine hcl 100 mg	3.23	19.65	16.42
J0744	Ciprofloxacin iv	3.06	19.49	16.43
J9260	Methotrexate sodium inj	2.90	19.33	16.44
J0696	Ceftriaxone sodium injection	2.56	19.01	16.45
J0461	Atropine sulfate injection	2.32	18.78	16.45
J7030	Normal saline solution infus	2.15	18.61	16.46
J7060	5% dextrose/water	2.15	18.61	16.46
J2780	Ranitidine hydrochloride inj	2.04	18.50	16.46
J1885	Ketorolac tromethamine inj	1.95	18.42	16.47
J7120	Ringers lactate infusion	1.91	18.37	16.47
J1644	Inj heparin sodium per 1000u	1.81	18.28	16.47
J3480	Inj potassium chloride	1.72	18.19	16.47
J2150	Mannitol injection	1.68	18.16	16.48
J2550	Promethazine hcl injection	1.65	18.13	16.48
J1815	Insulin injection	1.54	18.02	16.48
J8540	Oral dexamethasone	1.53	18.01	16.48
J2270	Morphine sulfate injection	1.29	17.78	16.49
J1100	Dexamethasone sodium phos	1.26	17.75	16.49
J2405	Ondansetron hcl injection	1.20	17.69	16.49
J3475	Inj magnesium sulfate	1.16	17.65	16.49
J7040	Normal saline solution infus	1.07	17.57	16.50
J7042	5% dextrose/normal saline	0.99	17.49	16.50
J9250	Methotrexate sodium inj	0.84	17.35	16.50
J2060	Lorazepam injection	0.81	17.31	16.50
J7050	Normal saline solution infus	0.73	17.23	16.51
J2765	Metoclopramide hcl injection	0.72	17.23	16.51
J1200	Diphenhydramine hcl injectio	0.51	17.03	16.51
Q0163	Diphenhydramine HCl 50mg	0.25	16.78	16.52
J0171	Adrenalin epinephrine inject	0.18	16.70	16.53

TABLE 3_Medicare Part B Payment Model
Oncology Drugs Underwater (Reimbursed Less Than Acquisition Cost)

Actemra	Keytruda
Adcetris	Kyprolis
Alimta	Lupron
Aranesp	Neulasta
Avastin	Nplate
Cyramza	Octagam
Dacogen	Opdivo
Elitek	Perjeta
Erbitux	Privigen
Faslodex	Provenge
Feraheme	Remicade
Folotyn	Rituxan
Fusilev	Sandostatin
Gammagard	Somatuline depot
Gammaked	Torisel
Gazyva	Treanda
Halaven	Trisenox
Herceptin	Tysabri
Injectafer	Vectibix
Istodax	Velcade
Ixempra	Vidaza
Jevtana	Xgeva
Kadcyla	Yervoy
	Zaltrap

List contains 47 oncology treatment or treatment related (e.g., supportive care) drugs. Drugs are underwater – that is, reimbursed at less than acquisition cost – based on the CMS Medicare Part B Drug Payment Model rate of ASP + 2.5% and $16.80, which with the Medicare 2% sequester cut is ASP + 0.86% and $16.53. This analysis, based on actual practice costs, compares reimbursement to acquisition costs only by drug; not other drug overhead and human resource costs of drug procurement, storage, inventory, preparation, and waste disposal that are not separately reimbursed but need to be covered by the drug reimbursement rate. The list would be far longer if these other costs were considered.

TABLE 4_Medicare Part B Payment Model: Increases in Controlled Substanc

Generic	Brand	J Code	J Code Unit	Dosing	Current Reimbursement ASP + 4.304%	ir
Vivitrol		J2315	1 mg	380	1197	
Morphine sulphate injection		J2270	10 mg	Between 2.5 to 20mg every 4 hours (10mg used here)	0.99	
Morphine preservative free		J2274	10 mg	Between 5 to 20mg every 4 hours (10mg used here)	8.1	
Hydrocodone		J1050	1 mg	2.5 to 10 mg every 4 to 6 hours (5mg used here)	1.75	
Fentanyl		J3010	.1 mg	50 to 100 mcg every 1 to 2 hours	0.49	
Hydromorphone	Dilaudid	J1170	up to 4mg	1 to 4 mg every 4 to 6 hours	1.93	
Meperidine	Demerol	J2175	100 mg	50 to 75 mg every 3 to 4 hours	4.3	
Methadone	Dolophine	J1230	up to 10mg	2.5 to 10 mg every 3 to 4 hours as needed	11.7	

EXHIBIT 2

Over 14 Years *of* Making A Difference In Cancer Care

Bad Medicine: Oncologists Review the Evidence Driven Drug Pricing Project's Report on the Medicare Part B Experiment

A recently released report from Memorial Sloan-Kettering Cancer Center's (MSK) Evidence Driven Drug Pricing Project (EDPP) is a clinically incoherent, agenda-driven, and dangerous analysis of oncology care and patient drug choices. This issue brief presents an examination of the "Part B Payment for Drugs in Medicare: Phase 1 of CMS' Proposed Pilot and Its Impact on Oncology Care" report by an expert review panel of practicing medical oncologists.

The quality of analysis and poor understanding of oncology care presented in this report by the MSK team is extremely disappointing. One might expect that a report from a cancer care institution such as MSK would have a plethora of experienced medical oncologists available to comment on the decision making process when formulating chemotherapy treatment plans for patients. Unfortunately, that does not seem to be the case, as none of the report's authors appear to have any significant relevant experience.

For instance, the report's lead author, Dr. Peter B. Bach, is not a medical oncologist but rather board certified in internal medicine, pulmonary medicine and critical care medicine. He does not provide chemotherapy treatment to cancer patients, and does not make the drug choices necessary to formulate treatment plans. The remaining co-authors are a hematology/oncology fellow with less than a year of clinical experience, an assistant research biostatistician, and data assistant.

There are a multitude of valid opinions on the ongoing drug pricing debate and Federal policymaking that must be considered. But first and foremost, the data upon which decisions are made must be truthful and accurate. Millions of patients with cancer in the Medicare program will be impacted by the changes proposed to the Part B program that this report is analyzing. Policymakers cannot be misled.

Drug Choices: Comparing Apples to Oranges

Clinical pathways are evidence-based treatment protocols designed to manage patient care and reduce costs without reducing the quality of care. The use of pathways is widely accepted by oncologists. Increasingly, payors are considering pathways in oncology when contracting with providers as a mechanism to improve quality, reduce variability, and decrease costs.[1]

When formulating a treatment plan, the practicing medical oncologist considers the pathways with his or her knowledge of the patient's medical and treatment history, and known drug complications and/or interactions. This includes such specifics as the patient's age, weight, comorbidities, and psychosocial considerations. This enables customized treatment protocols geared towards successfully beating the cancer while providing high quality of care and life.

To properly review the drug substitutions suggested in the report, an expert review panel of five medical oncologists on the board of the Community Oncology Alliance (COA) with a combined 86 years of experience was assembled. They evaluated the suggested pathways and drug substitutions for all factors relevant to quality of care and best outcome. Their findings were alarming.

EXHIBIT 2

General Findings

Rarely are two drugs interchangeable. Indications differ. Side effects differ. A patient's health, co-morbid conditions, or ability to tolerate the side effects may differ. The drug substitutions suggested in the MSK report takes little of that into consideration. They have widely differing indications and have never had any head-to-head studies published to verify equivalency.

The substitutions suggested in the report do not represent optimal or even equivalent cancer care. It appears that in making suggested drug substitutions, cost has exerted inordinate influence at the cancer patient's expense. In fact, while the drug costs may be lower, the likely costs to treat the resulting known side effects and predictable adverse events will more than surpass any savings. Coupled with the long-term detrimental effect on patient health and mortality, many of the substitutions do not represent optimal care.

Non-Small Cell Lung Cancer: Paclitaxel (Taxol) + Carboplatin versus Alimta + Cisplatin

The report suggests that paclitaxel (Taxol) and carboplatin is a comparable regimen to Alimta and cisplatin. That is absolutely not the case. First and foremost, there is no data that shows these two regimens to be equivalent. In fact, they are very different regimens with differing indications that are dependent on the type and stage of the lung cancer. The report advocates a clinically inferior treatment regimen while implying the only substantive difference is cost.

Specifically, a carboplatin and paclitaxel regimen has a high incidence of alopecia (hair loss) and neuropathy. For many patients there is a value to being able to continue life as 'normal' and without the added stressors of having to shop for a wig or be unable to drink a cup of coffee because they have lost feeling in their hands.

A cisplatin-based regimen also has a much higher toxicity and is a regimen that many cancer patients – including the elderly or those with decreased renal function, neuropathy, or hearing loss – cannot tolerate.

The estimated cost of the substitute carboplatin and paclitaxel regimen does not include the added cost of Avastin, which is typically used with this regimen to improve the results. Also, the preferred drug combination with Alimta is not cisplatin because of its much higher toxicity; an Alimta and carboplatin regimen is a safer, less toxic choice that would avoid side effects, improve quality of life, and lessen patient suffering.

Breast Cancer: Paclitaxel versus Abraxane

The report incorrectly suggests that paclitaxel is a comparable regimen to Abraxane for breast cancer. Few practicing medical oncologists would agree.

In addition to risk of severe anaphylaxis and death that can result from paclitaxel, Abraxane does not require administering pre-medications such as steroids (an issue in diabetic patients) or antihistamines (may have side-effects and impairs driving). And most importantly, there is no clinical data to establish equivalency for the substitution.

Finally, many patients with metastatic breast cancer will have already received paclitaxel in the adjuvant setting. No one would recommend re-treating a patient with paclitaxel when Abraxane has been demonstrated to be effective.

Colon Cancer: Avastin or Erbitux

The report suggests that Avastin is a comparable regimen to Erbitux for colon cancer. These drugs are not interchangeable and have completely different pharmacological elements and mechanisms of action.

Avastin blocks VEGF (vascular endothelial growth factor) receptors involved in both vasculogenesis (the formation of the circulatory system) and angiogenesis (the growth of blood vessels from pre-existing vasculature). Erbitux is a chimeric monoclonal antibody targeting EGFR (epidermal growth factor receptor).

Patients with a history of bleeding or thrombosis, recent surgery, proteinuria, or severe hypertension are not able to receive Avastin. Other patients may not be candidates for Erbitux because it can cause severe diarrhea, KRAS mutation status, and dermatological problems.

Of course, all of this is moot because patients who are candidates for Erbitux will often eventually require treatment with Avastin. By treating with both drugs patients have an additional treatment option they otherwise would not, thus increasing their chances of survival.

EXHIBIT 2

Cost of Care Differentials Between Settings: Community Oncology, Hospital Outpatient Departments, and PPS–Exempt Cancer Hospitals

Most cancer patients are treated in one of three settings. The majority, almost 70%[2] are treated in an office-based, or community oncology, setting. Another approximately 20% of patients are treated in community and teaching hospital outpatient departments (HOPD) based cancer centers. The remaining patients are treated in one of the 11 prospective payment systems (PPS)-Exempt Cancer Hospitals, also known as PCHs.

The cost of cancer care can vary substantially depending on the type of facility in which a patient is treated. The cost of care in the community oncology setting is the lowest and the highest in PPS–Exempt Cancer Hospitals. It is important to note that while criticizing community oncology where the cost of care is most efficient, Dr. Bach and his colleagues are at MSK, one of the PPS–Exempt Cancer Hospitals where the cost of care is higher and less efficient.

Multiple studies confirm that chemotherapy in the community oncology setting, regardless of drug choice, has a significantly lower cost than the same care when provided in a hospital-based setting. The Moran Company confirms that on a per-beneficiary basis, hospital chemotherapy administration spending was 42% higher in 2009, 67.8% higher in 2010, and 51.1% higher in 2011 than physician office chemotherapy administration spending.[3] A recent report by the actuarial firm Milliman found that hospital outpatient department costs for chemotherapy per-episode and per-session were 28% to 53% higher than the same treatment provided in the community oncology setting.[4]

A recent GAO study found that because Medicare reimburses PPS–Exempt Cancer Hospitals based on their costs, they have little incentive for efficiency and can actually increase profits by increasing the cost of care.[5] The GAO recommended that Medicare should consider paying these hospitals – including MSK – the same it pays other hospitals to encourage efficiency and avoid overspending.[6]

This point is well made in the MSK report in Figure 2 on Page 6 which shows that payments to community oncology practices are less than half those made to hospitals, including both 340B and non-340B facilities. Yet, paradoxically, the report fails to mention the tremendous cost savings community oncology presents to the U.S. health care system.

ASP + 6%: It's Not "Profit"

Currently Medicare reimburses providers at the Average Sales Price plus 6% (ASP + 6%). Since 2013, sequestration has further reduced that to 4.3%. The fundamental premise of the report states "That bill [for chemotherapy] has two parts: a reimbursement based on the average price of the drug, and a percentage based mark-up, or profit."

The 6% is not and never has been a "profit." The Centers for Medicare and Medicaid Services (CMS) does not describe the 6% as profit. The characterization by the report of the 6% as profit is wrong and biases the flawed conclusions that are the substance of entire the report.

In fact, Dr. Ezekiel J. Emanuel, a noted oncologist and bio-ethicist, commented in a New York Times Opinion, Aug. 8, 2011, "The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA 2003) … required Medicare to pay the physicians who prescribed the drugs based on a drug's actual average selling price, plus 6 percent for handling."

The 6% is intended to cover the costs associated with things such as the purchase, storage, administration, and disposal of toxic chemotherapy drugs. For many practices today, the 6% does not fully cover the cost of administering chemotherapy drugs. For many drugs, the acquisition cost is higher than the reimbursement due to wholesale discounts not passed on to providers and the sequestration deduction.

What Do Oncology Practices Use ASP + 6% For? Not profit.

The 6% is not profit, but rather covers services required for the safe delivery of chemotherapy not covered by existing reimbursement systems. This includes:

- Chemotherapy drug refrigeration and storage
- Drug mixing and preparation, including equipment, staff, and supplies
- Disposal of toxic chemotherapy waste.
- Treatment area staffing, in many cases including a portion of the cost of an oncology nurse, and equipment
- Cognitive services that are needed such as nutrition services and most general social work/advocate services
- Treatment planning and counseling
- Care coordination
- Supportive care, palliative, and end of life care
- Financial counseling

EXHIBIT 2

Providers are underwater on the drugs themselves before any of the related expenses. For all drugs, even those for which the acquisition cost is covered, the handling fee covers some but not all of the costs associated with providing chemotherapy. Oncologists rely on marginal revenue from drug payments to make up the difference. Thus, drastic reductions in the drug payments jeopardize the ability of oncologists to deliver the therapies.[7]

It should be noted that expenses related to chemotherapy not covered by the 6% were to be reimbursed through the establishment of CPT billing codes promised following implementation of MMA 2003. Today, 13 years later, many of these codes still have not been established. This leaves providers with no mechanism to bill for services rendered in the course of chemotherapy and its related activities. Providers must therefore rely on the 6% to cover all associated expenses.

In 2010, COA worked collaboratively with Avalere Health to design and administer a detailed survey to identify the complete suite of services performed by community oncology practices and to capture detailed costs associated with all aspects of delivering high quality cancer care. When comparing the difference in current Medicare reimbursements to practice costs, Avalere found that the practices sampled would receive payment equivalent to 56.53% of the costs they incurred to provide infusion services.[8]

The implication by the MSK report notwithstanding, drug reimbursement at a rate of ASP plus 4.3% cannot be construed as "profit" when more than 56% of the costs of the services associated with providing chemotherapy are not reimbursed at all.

Summary

Dr. Siddhartha Mukherjee, author of the 2011 Pulitzer Prize winning book, *The Emperor of All Maladies: A Biography of Cancer*, comments on the motivation and contribution of community oncologists in this manner, ". . . community oncologists are really the frontline of cancer medicine. I have enormous respect for community oncologists because much more than oncologists at tertiary care centers, they see the full range and breadth of the disease. When I was [working] in Boston, the one person's judgment who I trusted almost universally was the very first oncologist that the patient often saw, and this often was a community oncologist. They had a real sense of what was happening not only medically to the person, but also socially, emotionally, and so forth, and made a very valuable ally in treating a patient."[9]

Many of the newest cancer drugs, which currently have no alternative, have achieved unprecedented survival rates and advanced the state of patient care. Inevitably, advances in cancer care will collide with the cost of new drugs – innovation leads to new drugs that often come with higher costs. The high cost of oncology is an issue that must to be addressed by industry, providers, patients, and policymakers. However, to simply avoid drugs that are proven to save lives simply as a means to control costs is an unethical violation of the Hippocratic oath, which physicians have sworn to uphold.

While probably well intentioned, this MSK report is fundamentally flawed because it is based on the faulty premise that physicians put profits over patient care. There is absolutely no evidence to suggest that community oncologists select drugs based on profit rather than on patient care. There is ample evidence to suggest that by evaluating patient status, potential side effects, and presumed outcomes, community oncologists consistently base drug selection on quality of care. To imply otherwise is an affront to the thousands of oncologists, oncology nurses, and affiliated cancer care professionals in America, of which Dr. Bach and his colleagues are most certainly not.

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[3] The Moran Company; Cost Differences in Cancer Care Across Settings; August 2013.
[4] Milliman; Comparing Episode of Cancer Care costs in Different Settings: An Actuarial Analysis of Patients Receiving Chemotherapy; August 2013.
[5] Unites States Government Accountability Office; Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency; February 2015.
[6] Ibid.
[7] Journal of Oncology Practice; The Long Battle Over Payment for Oncology Services in the Office Setting; Joseph S. Bailes, MD, Terry S. Coleman, JD; January 2014
[8] Avalere Health; Providing High Quality Care in Community Oncology Practices/An Assessment of Infusion Services and Their Associated Costs; February 2010.
[9] Oncology Nursing News; Interview with Siddhartha Mukherjee, Author of The Emperor of All Maladies; Christin Melton; March 4, 2011.